IN THE SUPREME COURT OF THE STATE OF MONTANA
Case No. DA 10-0029

PEGGY STEVENS,
Plaintiff/Appellee,

vs.

NOVARTIS PHARMACEUTICALS CORPORATION,
Defendant/Appellant.

APPELLANT'S REPLY BRIEF

ON APPEAL FROM THE FOURTH JUDICIAL DISTRICT COURT
MISSOULA COUNTY, THE HONORABLE JOHN LARSON PRESIDING

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Table of Contents

Table of Authorities

Cases **Page(s)**

Statutes

Other Authorities

Summary of Argument

Limitations

Stevens wrongly asks this Court to rewrite Montana law in a manner that directly conflicts with Montana statutes and the multiple decisions of this Court that reject "discovery rules" in construing limitations periods. Stevens' alternative argument that her limitations period was tolled during the pendency of a failed foreign class action (about which she was not even aware) has been overwhelmingly rejected nationwide and should be rejected here. NPC is entitled to entry of judgment in its favor or a new trial.

Duty to Warn

In Montana, a drug manufacturer's duty to warn is discharged by an adequate warning to the prescribing physician, the learned intermediary. Stevens' claim that Montana has adopted the Restatement (Third), including a section requiring a drug manufacturer to warn such healthcare providers as nurses and non-prescribing doctors, is wrong. The trial court erroneously instructed the jury on this fundamental point, which requires a new trial.

Exclusion of Prior Inconsistent Statements

Montana recognizes the right of litigants to cross-examine party-opponents and other witnesses with prior inconsistent statements in pleadings and discovery responses. A party to a legal action may *not* escape cross-examination merely because she did not sign the statement at issue but instead had counsel do so.

Stevens and two key witnesses claimed wildly different facts at different stages of this proceeding, and the trial court's evidentiary error in excluding those changed stories requires a new trial.

Denial of Motion to Amend Answer

Even though Stevens refused to inform NPC of the value of her settlement with Dr. Schmidt so that NPC could make an informed decision whether to seek apportionment or post-trial setoff, NPC fairly and promptly moved to amend its answer to make an apportionment claim against Dr. Schmidt – as it had a statutory right to do. The trial court's erroneous denial of the amendment warrants a new trial.

Proximate Causation

Stevens failed to prove an essential link in her proximate causal chain – that a different warning would have made any difference to her outcome. Her ONJ allegedly was triggered by an invasive dental surgery, and such surgery was unavoidable.

Testimony About A Subsequent Remedial Measure

The trial court wrongly allowed staff nurse Joni Landes to testify about a subsequent remedial measure – a product labeling change that postdated Steven's injury – that Stevens claimed would have prevented her injury if made earlier.

Cross-Appeal

Motion to Amend Complaint

The trial court acted within its discretion in denying Stevens' untimely motion to amend, because the court was aware that Stevens had known the facts that formed the basis of her amendment for months, trial was imminent, and allowing the amendment would have unfairly introduced multiple new factual and legal issues into the case.

Dismissal of Claim Against Patrick Doyle

No claim against sales representative Doyle was viable, because his alleged misconduct – not passing on his employer's warning fast enough – was within the scope of his employment.

Social Security Setoff

The trial court's reduction of the verdict for future social security payments was required by Montana statute.

Argument

I. Stevens' suit against NPC is barred by the statute of limitations.

A. Montana's fictitious name statute does not excuse Stevens' untimely claim against NPC because Stevens knew NPC's name before filing her original complaint.

To accept Stevens' interpretation of the fictitious name statute, the Court must:

(1) Reject its own canon of statutory interpretation – and that of the Legislature – that when a statute is clear and unambiguous, a court will apply it as written;

(2) Contravene its own rejection – and that of the Legislature – of tolling to permit discovery of causes of action; and

(3) Ignore the fictitious name statute itself and the case law interpreting it.

1. Montana law forbids adding terms to a statute.

In her Answer, Stevens has not addressed the argument that her rewriting of the fictitious name statute violates the plain language of two Montana statutes and Montana's canons of statutory interpretation.

The plain language of two statutes is implicated here. MCA § 27-2-102(2) provides the general rule: "Lack of knowledge of the claim or cause of action, or of its accrual, by the party to whom it has accrued does not postpone the beginning of the period of limitation." MCA § 25-5-103, the fictitious name statute, provides that a plaintiff who "does not know the name of the defendant" may amend a claim "when the defendant's true name is discovered."

The trial court was not free to add to or delete from either statute, or to ignore either. *See* MCA § 1-2-101 (court must "give effect to all" statutory provisions, if possible, when there are several). This Court has held six times this year alone that when "the language [of a statute] is clear and unambiguous no further interpretation is required." *See, e.g., State v. Roberts*, 2010 MT 110, ¶ 10, --- Mont. ---; (*see also* Reply App'x 1 (collecting cases); Brief 16.) [1]

2. Montana rejects a "discovery rule" for statutes of limitations.

Stevens asks the Court to ignore any case that does not specifically interpret the fictitious name statute, but both MCA § 27-2-102(2) and the Court's jurisprudence are generally applicable to *all* limitations issues and reject tolling while a cause of action is discovered. (*See* Brief 14.) In *Bennett v. Dow Chemical Co.*, 220 Mont. 117, 122, 713 P.2d 992, 995 (1986), a toxic exposure personal-injury case, plaintiff urged the court to find that his discovery of his cause of action – rather than learning the cause of his injury – triggered the personal-injury statute of limitations. The Court refused, "expressly declin[ing] to extend discovery doctrine to toll statutes of limitation until discovery of legal rights."

[1] *Compare* MCA § 25-5-103 ("does not know the name of the defendant"); *Molina v. Panco Const., Inc.*, 2004 MT 198, ¶ 8, 322 Mont. 268, 95 P.3d 687 (plaintiff given wrong corporate title by responsible state official); *Sooy v. Petrolane Steel Gas, Inc.*, 218 Mont. 418, 708 P.2d 1014 (1985) (interpreting relation-back clause).

Stevens quotes *Bennett* as holding that "a statute of limitations can be tolled until a plaintiff discovers the legal cause of his injury if equity so dictates." (Answer 21 (quoting *Bennett*, 220 Mont. at 121, 713 P.2d at 995).) But that quote described a holding of a 1970 federal district court case, not a ruling in *Bennett*. *Id.* (citing *Hornung v. Richardson-Merrill, Inc.*, 317 F. Supp. 183 (D. Mont. 1970); discovery that an injury may have been caused by a drug is "the farthest reaches of discovery doctrine in Montana"). The *Bennett* holding was unequivocal – no tolling for "discovery of legal rights" – and its review of Montana law was comprehensive: "there is no Montana precedent for utilizing discovery doctrine to toll the statute of limitations beyond the discovery of the cause of an injury." *Id.*

3. Montana does not allow a plaintiff to designate a defendant by a fictitious name when she knows its name.

Franchi v. City of Helena is the only Montana authority applying the relevant, unambiguous portion of the fictitious name statute. In that case, as this one, the plaintiff knew the defendant's name but claimed he was "ignorant of facts giving rise to the [defendant's] liability." No. BDV-04-262, 2005 Mont. Dist. LEXIS 529, at *5-6 (D. Mont. Mar. 16, 2005). The court held that the fictitious name statute was "very clear" and dismissed the untimely claims.

Other states follow the Montana rule as applied in *Franchi*. For example, in *Erwin v. Bryan*, No. 2009-0580, --- N.E.2d ---, 2010 WL 2134560 (Ohio May 25, 2010), an Ohio Supreme Court case decided after NPC filed its opening brief, the

court applied its fictitious name statute, which is in relevant part exactly the same as Montana's and which is governed by the same principles of statutory construction as Montana's, *see Erwin*, 2010 WL 2134560, at *5 ("If a court rule is unambiguous, we apply it as written."). In *Erwin*, plaintiff filed a complaint against a doctor and several John Doe defendants, alleging negligent failure to timely diagnose. *Id.* at *3. Plaintiff subsequently learned that a second doctor also may have been liable, and so amended her complaint. The Ohio Supreme Court affirmed summary judgment in favor of the second doctor based on limitations, holding that "[b]ecause [plaintiff] knew [the second doctor]'s name, she did not have the option to designate him as a John Doe defendant in the original complaint, notwithstanding the fact that she had not identified him as being responsible for her husband's death." *Id.* at *7. The court emphasized the plain language of the rule:

> According to its unambiguous language, [the fictitious name rule] provides that a plaintiff may designate a defendant in a complaint by any name and description when the plaintiff does not know the *name* of that party. Thus, [the fictitious name rule] does not permit a plaintiff to designate a defendant by a fictitious name when the plaintiff actually knows the name of that defendant.

Id. at *5.

Stevens asks the Court to ignore unambiguous Montana statutory language and apply California law, but California, unlike Montana, *favors* discovery rules. *See, e.g., Norgart v. Upjohn Co.*, 981 P.2d 79, 88 (Cal. 1999) (California recognizes "discovery rule" for plaintiff to discover her cause of action, which may

be expressed by statute or implied by courts). Regardless, the fictitious name statute would not save Stevens' claim even in California. *Maxwell v. Honeycutt*, No. B199280, 2008 WL 643146 (Cal. Ct. App. Mar. 11, 2008), is illustrative: the court held that the statute did not apply because plaintiff knew the defendant's identify and knew that he had treated the plaintiff. *Id.* at *5. The court rejected plaintiff's argument that he was not obliged to sue earlier because he did not know of defendant's negligence until he had obtained a complete set of medical records. *Id.* Precisely the same reasoning applies here, where, before filing her original complaint, Stevens indisputably knew: (1) she had been treated with Zometa®, (2) Zometa® was a NPC drug, and (3) she had not been warned about the risk of ONJ in connection with a tooth extraction. (*See* Brief 19-20.)[2]

Stevens refers the Court to Mississippi and Alabama, citing *Dannelley v. Guarino*, 472 So. 2d 983 (Ala. 1985), and *Womble v. Singing River Hospital*, 618 So. 2d 1252 (Miss. 1993). Even if this Court considers these states' statutes, the cases support NPC's position. In *Womble*, the court held that plaintiffs were not ignorant of defendants' identities as a matter of law because defendants' names appeared throughout the medical records. 618 So. 2d at 1267. In *Dannelley*, the

[2] *See also, e.g., Dover v. Sadowinski*, 194 Cal. Rptr. 866, 869 (Cal. Ct. App. 1983). In *Dover*, the fictitious name statute did not apply because plaintiff's attorneys knew the defendant's identity, though they said – as Stevens' attorneys do here – that they did not know how "deeply" the defendant was involved.

court emphasized that the fictitious name rule "was not meant to excuse ignorance of the identity of a cause of action, but only ignorance of the name of the party against whom a cause of action is stated." 472 So. 2d at 986 (citation omitted); *see also Marsh v. Wenzel*, 732 So. 2d 985, 989 (Ala. 1998) (same).

B. The trial court wrongly refused to instruct the jury on limitations.

Stevens contends that NPC was not entitled to an instruction on limitations because the trial record did not support it. (Answer 22.) In fact, NPC elicited testimony sufficient to bring the issue to the jury. (*See* Brief 15, 19 n.4 (citing trial testimony and admissions regarding Stevens' knowledge of NPC's identity and her injury).) Stevens may not make this argument in any event because she never made it to the trial court – to the contrary, she proposed her *own* instructions on limitations, but argued that the statutory interpretation should be resolved by the court. (Tr. 1785:9-1786:3.)

C. The limitations period was not tolled by a failed putative federal personal-injury class action.

Stevens argues that, even if otherwise untimely, her claim against NPC was saved because an unrelated plaintiff who filed an unrelated Zometa case in federal court in Tennessee in 2005 included in her complaint a request that a worldwide personal-injury class should be certified. Stevens offered this "tolling" defense to NPC's limitations argument for the first time *after* the trial court had already

denied NPC's motion to dismiss based on limitations (and the trial court never ruled on it).[3]

Stevens says the U.S. Supreme Court's opinion in *American Pipe* "both permits and encourages class members to rely on the named plaintiffs to press their claims." (Answer 25); *see Am. Pipe & Const. Co. v. Utah*, 414 U.S. 538, 553-54 (1974) (tolling rule prevents unnecessarily duplicative "protective" filings, which would be detrimental to class action procedure's purposes of efficiency and economy); *Crown, Cork & Seal Co. v. Parker*, 462 U.S. 345, 350-51 (1983) (tolling rule is designed to avoid "needless multiplicity of actions"); *Maestas v. Sofamor Danek Grp., Inc.*, 33 S.W.3d 805, 808 (Tenn. 2000) ("The rationale for [the tolling] rule is that if the statute of limitations were not tolled, that single system would be burdened both by the class action litigation and by numerous protective filings from the members of the class seeking to preserve their rights to bring suit individually should class certification be denied."). But Stevens is not asserting that she waited to file her personal-injury claim against NPC based on the pendency of a putative class action. Indeed, her claim is exactly to the contrary – she says *she did not even know* that she should sue NPC until 2009.

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[3] *Compare* Pl.'s Opp. Mot. Dismiss *with* Pl.'s Opp. Mot. Summ. J. Stevens misstates the law by arguing that NPC waived its right to address tolling. *See, e.g., People v. Whitfield*, 888 N.E.2d 1166, 1173 (Ill. 2007) (appellant need not anticipate). Stevens bears the burden of proof on tolling. *See Israelson v. Mountain Tractor Co.*, 155 Mont. 69, 73, 467 P.2d 149, 151-52 (1970) (party claiming exception to statute of limitations has burden).

Regardless, all of the tolling cases that Stevens cites in the first three pages of her argument, including *American Pipe*, relate to the question – not posed here – of whether a putative class action filed in one jurisdiction tolls the limitations period for plaintiffs filing suit *in the same jurisdiction*. (*See* Answer 24-25.) Montana has never addressed whether it would accept even such intra-jurisdictional tolling. The different question that Stevens raises is whether a putative class action filed in one jurisdiction tolls the statute of limitations extra-territorially, that is, in every other possible jurisdiction where a plaintiff might file suit. No such rule of law has ever been adopted by Montana, the U.S. Supreme Court has never considered it,[4] and most states that have ever considered the concept have rejected it.

The doctrine has been rejected under the law of Alabama, Arizona, California, the District of Columbia, Florida, Hawaii, Illinois, Indiana, Kentucky, Maryland, New Mexico, New York, Pennsylvania, Puerto Rico, South Dakota, Tennessee, and Texas, and rejected in antitrust or securities contexts in Alaska, Idaho, Kansas, Louisiana, Montana, Oregon, Utah, and Wyoming. (*See* Reply App'x 2 (enumerating cases).)

[4] *Portwood v. Ford Motor Co.*, 685 N.E.2d 941, 944 (Ill. App. Ct. 1997) ("[T]he United States Supreme Court ... has [not] yet spoken on the issue of cross jurisdictional tolling.").

One reason for the broad rejection of the concept is that, unlike tolling within a jurisdiction, cross-jurisdictional tolling is not consistent with the interests of a state that adopts it. *See Maestas*, 33 S.W.3d at 808 (declining to adopt cross-jurisdictional tolling, and noting that "Tennessee simply has no interest, except perhaps out of comity, in furthering the efficiency and economy of the class action procedures of another jurisdiction, whether those of the federal courts or those of another state"). Cross-jurisdictional tolling also presents federalism and sovereignty concerns:

> [A]doption of cross-jurisdictional tolling would ... make the commencement of [one state's] statute of limitations contingent on the outcome of class certification as to any litigant who is part of a putative class action filed in any federal court in the United States. It would essentially grant to federal courts the power to decide when [the state's] statute of limitations begins to run. Such an outcome is contrary to [the state] legislature's power to adopt statutes of limitations and the exceptions to those statutes, and would arguably offend the doctrines of federalism and dual sovereignty. If the sovereign state ... is to cede such power to the federal courts, [the court should] leave it to the legislature to do so.

Id. at 809.

Stevens cites four cases purportedly accepting cross-jurisdictional tolling. (Answer 26-27.) In three of the four cases, the putative class action in question was a federal class action filed in the same state as the state action *and* there was an immediate and local connection between the plaintiff in the later-filed personal

injury action and the putative class.[5] In the fourth, the Ohio Supreme Court held that a plaintiff could use a federal class action to take advantage of an Ohio tolling statute that permits a plaintiff to file suit within one year of the dismissal of a prior suit "otherwise than upon the merits." *See Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 163 (Ohio 2002). *Vaccariello* did *not* hold that the underlying limitations period was tolled during the pendency of the putative class.[6]

The Court should not adopt and retroactively apply the doctrine of cross-jurisdictional tolling in this case. First, as discussed above, Stevens did not rely on the putative class action to postpone filing.

Second, this pharmaceutical personal injury case is an especially wrong vehicle for cross-jurisdictional tolling. *No* pharmaceutical personal injury class

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[5] *See Lee v. Grand Rapids Bd. of Educ.*, 384 N.W.2d 165, 166-67 (Mich. Ct. App. 1986) (federal class action in Michigan against local board of education on behalf of school employees in Grand Rapids; later action filed in Michigan by one of those employees); *Hyatt Corp. v. Occidental Fire & Cas. Co.*, 801 S.W.2d 382, 384 (Mo. Ct. App. 1990) (federal class action in Missouri was for injuries from skywalk collapse in Kansas City; later action was filed in Missouri by one of the injured parties); *Staub v. Eastman Kodak Co.*, 726 A.2d 955, 961 (N.J. Super. Ct. App. Div. 1999) (federal class action in New Jersey; New Jersey plaintiff was aware of class action, in touch with class action attorneys, and filed suit upon denial of certification of the class).

[6] Stevens does not and cannot claim the benefit of Montana's similar tolling statute. Montana's rule was borrowed from California in 1861, and so the Court should look to California law for interpretation. *See, e.g., Snow Country Const., Inc. v. Laabs*, 1999 MT 279, ¶ 12, 296 Mont. 520, 989 P.2d 847 (in interpreting vague provisions of statutes borrowed from California, court considers California law). California does not apply its one-year tolling statute to class actions. *See Robbin v. Fluor Corp.*, 835 F.2d 213, 215 (9th Cir. 1987) (reversing district court's tolling based on failed class action claim, and holding that California's statute "addresses neither class actions nor equitable tolling"). California also flatly rejects cross-jurisdictional tolling. *See Jolly v. Eli Lilly & Co.*, 751 P.2d 923, 933-38 (Cal. 1988) (en banc).

action has been certified over opposition and survived appeal in the federal system since the Supreme Court's decisions in *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999) and *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997). *See, e.g., Jolly v. Eli Lilly & Co.*, 751 P.2d 923, 933-38 (Cal. 1988) (en banc) (rejecting tolling due to pending class action even *within* California in the context of mass torts alleging personal injury because such torts are not susceptible to class action certification); *Bell v. Showa Denko K.K.*, 899 S.W.2d 749, 758 (Tex. App. 1995) (refusing to hold that the Texas statute of limitations was tolled by "the filing of a mass personal injury suit, in a federal court, in another state, with the variety of claims necessarily involved in such a case").[7] Given this legal backdrop, should the Court recognize cross-jurisdictional tolling here, it would render the limitations period impermissibly uncertain and would *encourage* unnecessary litigation, not deter it, by giving counsel everywhere an incentive to add putative class relief to every complaint just in order to toll statutes of limitations to the benefit of unknown future plaintiffs.

The same characteristics that make a pharmaceutical class action impossible to certify – the lack of crucial common characteristics among the class members, such as dates of use, what warnings were or were not transmitted to prescribing

[7] *American Pipe* involved a federal antitrust class action and *Crown, Cork & Seal* a federal employment discrimination class action.

physicians, alternative causation issues and the like – mean that the defendant is *not* adequately placed on notice by the existence of a putative class action of the identity of the plaintiffs or the nature of the specific claims they may face.[8] *See Jolly*, 751 P.2d at 936 ("The same reasons that render certification of mass-tort claims generally inappropriate render inappropriate the application and extension of *American Pipe* to the present case."). The putative class action on which Stevens relies is illustrative. The plaintiffs did not even attempt to certify the putative personal injury class from the original complaint: their eventual motion to certify was for a putative class of no-injury plaintiffs seeking only future dental monitoring, and was limited to certain named jurisdictions not including Montana. *In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760, 2007 WL 3012972, at *1 (M.D. Tenn. Oct. 10, 2007).

Third, Stevens (a personal-injury plaintiff from Montana) was not a member of the class, described above, for which certification was sought and so she should not benefit from any tolling. *See Smith v. Pennington*, 352 F.3d 884, 894 (4th Cir. 2003) (for tolling purposes, the relevant class is that for which certification is

[8] Stevens' Answer proves the gross uncertainty of a putative class's composition and the inadequate notice point. Three substantially identical complaints were filed on the same day, one for plaintiffs who received only Aredia® (*Wood*), one for plaintiffs who received only Zometa® (*Becker*) and one for plaintiffs who received both (*Anderson*). Stevens relies on *Anderson* in her Answer, but she was not a putative class member of *Anderson* because she never received Aredia®.

ultimately sought); *Sawtell v. E.I. du Pont de Nemours & Co.*, 22 F.3d 248, 253-54 (10th Cir. 1994) (same); *see also Ammons v. La-Z-Boy Inc.*, No. 1:04-CV-67-TC-SA, 2009 WL 3460306, at *5 (D. Utah Oct. 20, 2009) (same).

Fourth, the jurisdiction in which the class complaint on which Stevens relies was filed, Tennessee, has expressly rejected cross-jurisdictional tolling. It would violate NPC's due process rights to retroactively credit an action taken in one state in a way that substantively differs from the credit given it by the state in which the action was taken. *See Gibson v. Am. Cyanamid Co.*, No. 07-C-864, --- F. Supp. 2d ---, 2010 WL 2465498, at *2 (E.D. Wis. June 15, 2010) (state court's expansion of common-law tort liability, with retroactive application to the defendant, was sufficiently contrary to settled expectations that it violated defendant's due process rights and warranted dismissal). Had NPC reasonably anticipated that Montana, or any state, would deem its limitations period "tolled" by the pendency of the Tennessee suit, NPC could have, and would have, moved to strike the class allegations at the outset of that suit.

II. NPC is entitled to a new trial because the trial court's rulings made it impossible to demonstrate that NPC fulfilled its duty to warn.

A. The trial court erroneously instructed the jury that NPC had a duty to warn healthcare providers other than the prescriber Dr. Schmidt.

There is no reasonable dispute that Section 6(d) of the Restatement (Third) of Torts is not the law of Montana. In her Answer, Stevens block-quotes § 6(d) and claims that it is part of "the Restatement of Torts which has been repeatedly accepted and followed by the Montana Supreme Court." (Answer 30.) In fact, no section of the Restatement (Third) has ever been adopted by any Montana court. All the citations that Stevens assembled in an appendix to support her claim in fact refer to sections of the *Second* Restatement, a completely different document that includes the learned intermediary doctrine on which NPC asked the trial court to instruct the jury on. (*See* Pl.'s App'x 15); *see also* Pl.'s Opp'n Brief re Motions in Limine in *Boles v. Merck & Co.* at 1 (Reply App'x 3) (Fosamax ONJ plaintiff describing the Restatement (Third) as a "radical reshaping of decades of products liability law" and arguing against application of § 6).

In fact, Montana and virtually every other state follow the learned intermediary doctrine and provide that a drug manufacturer's duty to warn is to the prescribing physician and not to nurses like Joni Landes or to other non-prescribing doctors like Dr. Morris or the *locum tenens* physicians at Guardian Oncology. *See Hill v. Squibb & Sons, E.R.*, 181 Mont. 199, 206, 592 P.2d 1383,

1387-88 (1979) ("[T]he duty of a drug manufacturer to warn of the dangers inherent in a prescription drug is satisfied if adequate warning is given to the physician who prescribes it."); (*see also* Brief 26-28; Supp. App'x) A correct statement of the majority rule can be found in a Zometa® opinion unsealed after NPC's opening brief was filed, in which a New Jersey court rejected the precise position Stevens urges this Court to adopt. *See* April 30, 2010 Opinion, *Bessemer v. Novartis Pharms. Corp.*, No. MID-L-1835-08 (unsealed 6/8/10) (Reply App'x 4). The court rejected § 6(d) and "reject[ed] [p]laintiffs' notion that NPC had a duty to warn the dental community at large, or even [plaintiff]'s individual non-prescribing treating physicians." *Id.* at 21-23.

Stevens asks this Court to impose on NPC retroactively – in violation of NPC's due process rights, *see Gibson*, 2010 WL 2465498, at *7 – a new duty to warn non-prescribing healthcare providers such as staff nurses.[9] (Answer 32-33.) *None* of the four cases she cites – all from states other than Montana – involves a finding by the court that a manufacturer had a duty to warn any healthcare provider *other* than the prescribing physician. In *Larkin v. Pfizer, Inc.*, the Kentucky

[9] To the extent Stevens is now arguing that this Court should impose a *new, retroactive* duty to warn nurses and non-prescribing physicians, this would violate NPC's due process rights under the 14th Amendment. Stevens told the trial court that Montana *already* recognized such a duty. (Tr. 1770:21-23.) Because the court had earlier denied Stevens' motion to amend her complaint to add a claim that NPC owed a duty to warn Dr. Morris, *see infra* Cross-Claim § II, the adoption of the erroneous instruction also blindsided NPC, which had not prepared an expert or regulatory defense on the point.

Supreme Court adopted the learned intermediary doctrine and held that "the rule only identifies the party to be warned, i.e., *the health care provider who prescribes the drugs*." 153 S.W.3d 758, 770 (Ky. 2004) (emphasis added). In *Madsen v. American Home Products Corp.*, a federal district court predicted that Iowa would apply the learned intermediary doctrine and held that "Defendant was required to warn *only Plaintiff's prescribing physician* about the risks associated with the diet drugs." 477 F. Supp. 2d 1025, 1033-35 (E.D. Mo. 2007) (emphasis added). The New York trial court in *Tenuto v. Lederle Laboratories* discussed § 6(d) solely with regard to *which* warning should be provided, not to whom the warning should be given, 695 N.Y.S.2d 259, 262-64 (N.Y. Sup. Ct. 1999), and New York's highest court – in a decision not cited by Stevens – held the same year that a manufacturer's duty is discharged "by giving adequate warning to the prescribing physician." *Spensieri v. Lasky*, 723 N.E.2d 544, 549 (N.Y. 1999). *Tyler v. Squibb*, No. 8:10CV107, 2010 U.S. Dist. LEXIS 40268 (D. Neb. Apr. 23, 2010), notes only that Nebraska adopted § 6(d) in *Freeman v. Hoffman-LaRoche, Inc.* In *Freeman*, the court adopted the learned intermediary doctrine and accordingly held that a complaint alleging that the plaintiff's physician had not been warned was sufficient to survive a motion to dismiss. 618 N.W.2d 827, 842 (Neb. 2000).

Stevens argues that the verdict form cured the error by preventing the jury from finding NPC negligent for failing to warn Dr. Morris. (Answer 31.)[10] She misrepresents the verdict form to make her contention more plausible, quoting Question 1 as asking whether NPC was negligent "in its label or information to Dr. Judy Schmidt or Guardian Oncology treating professional staff (but no other healthcare provider)." (Answer 7.) The "but no other healthcare provider" language has been inserted by Stevens: neither it nor any equivalent appears in the verdict form. (Verdict Form #1; Tr. 2000:25-2001:4.) And even if Stevens' argument had been based on the actual verdict form, it could not render the court's error harmless for two different reasons.

First, considered simply on its own, as Stevens (wrongly) contends should be the case, Question 1 undeniably directs the jury to find liability if NPC failed to warn, *inter alia*, the *treating professional staff* at Guardian Oncology. Stevens' counsel took advantage of this incorrect question, and the corresponding incorrect instructions, to tell the jury that it did not matter if prescriber *Dr. Schmidt* received an adequate warning, and that the jury should instead find NPC liable for failing to warn nurse Landes and various non-prescribers at Dr. Schmidt's office:

> *When it gets down to it, what difference does it make* [if Dr. Schmidt was warned]? Because, as it turns out, Judy Schmidt wasn't even the

[10] Stevens' counsel elicited testimony that Dr. Morris had not been warned by NPC at the time he extracted Stevens' tooth. (Tr. 523:17-21.)

> person primarily providing Peggy Stevens' healthcare in the months immediately preceding her tooth extraction. She was being attended to by what they call locum tenens, visiting doctors: Dr. Hall, Dr. Yu. And as a practical matter, mostly being attended to by the nursing staff, the oncology nurses. *And no one, absolutely no one, has even suggested that any of them were aware of the causal relationship between Zometa, tooth extractions and osteonecrosis of the jaw.* Not one word of evidence in this entire case. All of the evidence in this case is to the contrary. *Joni Landes testified she didn't know about the complication until February of '05 after Peggy's tooth was extracted.*

(Tr. 1843:4-21 (emphasis added).)

Second, verdict forms and jury instructions in fact must be read as a whole. *Hall v. Big Sky Lumber & Supply, Inc.*, 261 Mont. 328, 332, 863 P.2d 389, 392 (1993). Jury Instruction 13 told the jury to find liability if adequate instructions were not provided "to prescribing *and treating healthcare providers* who are in a position to reduce the risks of harm ... *and other healthcare providers* who are in a position to reduce the risks of harm." (emphasis added). Instruction 14 told them that causation could be satisfied by a sufficient warning that "would have ... prompted her *or her medical providers* to take precautions...." (same). Question 2 of the verdict form – which would be answered by reference to Instruction 14 and the related instructions – asked "[w]as Novartis Pharmaceutical Corporation's negligence a substantial factor in causing injury to Peggy Stevens' jaw?" Stevens elicited testimony that it was, precisely because *non-prescribing* healthcare providers were not warned. In addition to the testimony and closing argument

discussed above regarding nurses and non-prescribing doctors at Guardian Oncology, Stevens' counsel deliberately elicited testimony that Dr. Morris had not been warned by NPC at the time he extracted Stevens' tooth. (Tr. 523:17-21.) She cannot now argue that this testimony was meaningless or could not have affected the jury's verdict. *Hall*, 261 Mont. at 334, 863 P.2d at 393 ("[B]ecause the trial court presented an instruction on a key issue of law which was incorrect as a matter of law, a reversal is required.").

Question 2 of the verdict form – which would be answered by reference to Instruction 14 and the related instructions and so by reference to the warnings NPC gave (or didn't give) all of Stevens medical providers – asked "[w]as Novartis Pharmaceutical Corporation's negligence a substantial factor in causing injury to Peggy Stevens' jaw?" The trial court's instructions on a key issue were clearly incorrect as a matter of law, and reversal is required. *Hall*, 261 Mont. at 334, 863 P.2d at 393.

B. The trial court erred by excluding all evidence of statements and allegations previously made by Stevens against Dr. Schmidt.

The pleadings, expert disclosures, and discovery responses that NPC sought to admit address factual issues, such as Stevens' assertion that Dr. Schmidt was actually aware of the risks of dental surgery in a patient on Zometa®. (*See* Brief 30.) Such factual statements are prior inconsistent statements, statements against interest, party admissions and judicial admissions and are "conclusive as against

the pleader, and ... admissible as against the party making them in the litigation as proof of the facts which they admit." *See Meadow Lake Estates Homeowners Ass'n v. Shoemaker*, 2008 MT 41, ¶ 45, 341 Mont. 345, 178 P.3d 81. That they were prepared by an attorney does not render them inadmissible, and the cases involving attorney affidavits that Stevens cites are irrelevant. *See Kohne v. Yost*, 250 Mont. 109, 112, 818 P.2d 360, 362 (1991) (attorney's "sayings and doings in the presence of the court concerning the trial of the cause are the same as though said and done by the party himself.").

C. The trial court erred by denying NPC's motion to amend its answer to assert an apportionment claim against Dr. Schmidt.

When two defendants have been sued under mutually exclusive theories of liability, a jury in Montana will, if it finds liability at all, apportion that liability between them. MCA § 27-1-703. Stevens' settlement with Dr. Schmidt triggered NPC's statutory right to elect between having liability apportioned between itself and Dr. Schmidt or having the verdict reduced by the settlement amount. *Id.* NPC acted promptly to learn the amount and terms of the settlement to enable it to make an informed election, and moved to amend its complaint as soon as Stevens refused to respond. (Brief 33-34.) The amendment should have been allowed.

III. NPC is entitled to judgment as a matter of law because Stevens failed to present evidence that her injury could have been prevented by a different warning.

The unequivocal testimony was that Stevens had to have dental work; no warning in the world could have prevented it. And Stevens could have had a root canal *only* in conjunction with a crown lengthening, an invasive dental procedure involving removal of bone. (Tr. 564:1-9, 548:12-549:17, 565:23-566:1; *see also* Brief 34.) Stevens' expert Dr. Marx testified that procedures invasive to bone trigger ONJ (Tr. 806:14-807:7) and *no* expert testified that a patient is at less risk of developing ONJ if she has (invasive) crown lengthening rather than an (invasive) extraction. Stevens has offered no factual or legal argument that the allegedly inadequate warning made any difference to Stevens' outcome, and NPC is entitled to judgment as a matter of law.

IV. NPC is entitled to a new trial because the trial court erroneously excluded Dr. Morris' MMLP answer, which established that Stevens' dental surgery was inevitable.

Dr. Morris pled in his Answer to the MMLP that Stevens' tooth extraction was "the only realistic treatment option" for her, and that he would have recommended it regardless of the risks of Zometa®. (Morris Answer 2 (Exhibit 1 to NPC's Submission of Evidence Proffered at Trial and Refused).) NPC was entitled to introduce this statement to impeach his conflicting trial testimony. Whether it was prepared by him or his attorney is of no consequence; in Montana,

"counsel's admissions are binding upon the client." *Kohne*, 250 Mont. at 112, 818 P.2d at 362.

Stevens argues that Dr. Morris' answer to the MMLP is somehow inadmissible because it is "confidential," citing a statute that bars the *director of the MMLP* from releasing records under subpoena. No statute prevents a party to an MMLP proceeding from voluntarily disclosing records in her possession, as Dr. Schmidt did at her deposition without objection by Stevens. (Tr. 531:11-536:15.) Even if otherwise "confidential," the document was admissible at trial; no other evidentiary rule would be consistent with NPC's constitutional rights. *Linder v. Smith*, 193 Mont. 20, 30, 629 P.2d 1187, 1192 (1981), makes the point, and Stevens' claim that *Linder* is applicable only to inconsistent *testimony* given before the MMLP cannot be reconciled with the policy and law underlying *Linder*. Moreover, Montana law clearly provides that pleadings may be used to impeach. *See, e.g., Fox v. Fifth W., Inc.*, 153 Mont. 95, 100, 454 P.2d 612, 615 (1969) (opposing party may introduce pleadings inconsistent with later assertions).

V. NPC is entitled to a new trial because the trial court erroneously allowed Stevens to use NPC's post-injury warnings to prove that its pre-injury warnings were inadequate.

Stevens claims "there was no mention by Joni Landes of any subsequent warning given by NPC." (Answer 46.) That is wrong: Landes testified when asked about NPC's package insert that "[t]hey still weren't giving a positive link to

[ONJ] until February 2005." (Tr. 1227:8-15; *see also* Brief 39.) This reference to a subsequent remedial measure by NPC violated Rule 407.

Stevens contends that she offered the evidence not with regard to liability but to establish that an adequate warning, if provided "to that office," would have been provided to Stevens. (Answer 48.) But Stevens' counsel argued: "[T]hey [the office] had no clue until February of 2005 after Peggy's tooth was extracted." (Tr. 1841:4-19.)

Cross-Appeal Argument

The court will reverse a denial of a motion to amend a complaint only if the trial court abused its discretion. *Deschamps v. Treasure State Trailer Court, Ltd.*, 2010 MT 74, ¶ 18, 356 Mont. 1, 230 P.3d 800. It reviews legal issues *de novo*. *In re Marriage of Szafryk*, 2010 MT 90, ¶ 18, 356 Mont. 141, --- P.3d ---.

I. The trial court did not abuse its discretion in denying Stevens' motion to amend her complaint.

"[A] motion to amend should be [filed] *as soon as the necessity for altering the pleading becomes apparent.*" *Mitchell v. Mitchell*, 169 Mont. 134, 139, 545 P.2d 657, 659 (1976) (emphasis added). Given the circumstances and the trial date Stevens had pressed to keep, the court was within its discretion in concluding she waited too long to file her motion to amend.

By April 3, 2009 at the latest, Stevens' attorneys were aware of the public Zometa®/ONJ litigation against NPC, which had been pending as an MDL since

April 2006. (*See* Notice of Filing Original Affidavit Regarding MDL Status (advising the district court and Stevens of the pending federal MDL involving Zometa®).) On May 20, 2009, the district court issued an order giving Stevens' Montana attorneys access to the discovery materials that the MDL attorneys had compiled. (Protective & Confidentiality Order.) On May 29, 2009, Stevens disclosed four new retained experts who had been previously retained by the MDL attorneys,[11] and on June 4, 2009, two MDL attorneys who for years had been dealing with documents, experts, and deposition testimony sought pro hac vice admission as co-counsel for Stevens.[12]

Thus, the district court was well within its discretion to reject the notion that Stevens' attorneys had to review "hundreds of thousands of pages of documentary evidence, not including thousands of pages of expert witness disclosures and deposition testimony" (Petition 14) beginning on May 20, 2009, before filing her motion to amend. In these circumstances, and with a trial date set in this "chess-clock" timed trial, the district court did not abuse its discretion when concluding that Stevens unduly delayed filing her motion. *See Hughes v. Pullman*, 2001 MT 216, ¶¶ 39-46, 306 Mont. 420, 36 P.3d 339 (affirming denial of motion for leave to file supplemental complaint because, *inter alia*, plaintiff doctor "waited three

[11] (*See* 5/29/09 Pl.'s Second Liability Expert Witness Disclosure (Reply App'x 6).)

[12] (*See* Motion for Pro Hac Vice Admission, Ex. 1-2.)

months after the revocation" of hospital privileges to assert claim based on revocation).

The district court also did not abuse its discretion in finding that an untimely amendment so close to trial also would have unduly prejudiced NPC, in this first ONJ case it had tried. NPC had been defending a specific set of claims in this case on a very fast track for seven months. Had the motion to amend been granted, NPC would have been required to prepare regulatory and factual defenses to new, materially different allegations, including the claim that NPC was required to warn someone other than the learned intermediary and the serious accusations that NPC engaged in willful and wanton conduct and deliberately distributed Zometa® in conscious and intentional disregard of a high probability of injury to Stevens, accusations that would have injected into this case the entirely new issue of intent, *see* MCA § 27-1-221 (requiring actual fraud or malice).

The trial court, already aware of the parties' positions regarding what issues were to be tried and what evidence was material to those issues, did not abuse its discretion in determining that NPC should not have been required to prepare what would have been a vigorous and substantial expert and corporate conduct defense to a punitive damages claim in the twenty-five days remaining in the discovery period and the sixty-eight days remaining before trial. *See Loomis v. Luraski*, 2001 MT 223, ¶¶ 43-44, 306 Mont. 478, 36 P.3d 862 (district court did not abuse its

discretion by denying the plaintiffs' motion to amend the pleadings to add a claim of easement by implication on top of their original claim of easement by necessity, noting that although the former is a subset of the latter, "the elements differ, and the defenses would differ"); *Knapp v. Whitaker*, 757 F.2d 827, 849 (7th Cir. 1985) (affirming denial of motion to amend complaint to allege punitive damages because "[t]he untimely filed punitive damages claim, if granted, would have clearly prejudiced the defendants who invested a year preparing their defense to the allegations pleaded, without any notice of a punitive damage claim").[13]

II. The trial court correctly dismissed the complaint against Patrick Doyle.

Stevens is wrong that NPC sales representative Patrick Doyle could be liable under Montana law for untimely passing along a warning provided to him by NPC. She cites MCA § 28-10-702(3) for the proposition that an agent can be independently liable for "wrongful" acts. (Answer 51.) In order to qualify for this "narrow exception" to the rule against individual liability, however, such acts must be of a "personal nature," *Crystal Springs Trout Co. v. First State Bank of Froid*, 225 Mont. 122, 129, 732 P.2d 819, 823 (1987), and be independent wrongs "outside the scope of [the] agency relationship," *Crane Creek Ranch, Inc. v.*

[13] Stevens may not "incorporate[] by reference" arguments made in her petition for supervisory control. *See Murphy Homes, Inc. v. Muller*, 2007 MT 140, ¶ 24, 337 Mont. 411, 162 P.3d 106 (rejecting attempt to incorporate arguments by reference); *State v. Cybulski*, 2009 MT 70, ¶¶ 14-15, 349 Mont. 429, 204 P.3d 7 (same); *State v. Ferguson*, 2005 MT 343, ¶ 41, 330 Mont. 103, 126 P.3d 463 (same).

Cresap, 2004 MT 351, ¶¶ 12-13, 324 Mont. 366, 103 P.3d 535. Passing along a warning that NPC gave him to pass on – however swiftly or slowly – was within the scope of Doyle's agency relationship with NPC, was not alleged to be otherwise, and does not give rise to liability. (*See* 4/7/09 Opinion & Order 7 (dismissing claim because, *inter alia*, Stevens did not allege that Doyle engaged in an independent wrong).)

III. The trial court correctly reduced the verdict by the amount of future social security payments.

The trial court properly reduced the verdict by the amount of future social security payments, as required by the statute, which provides that the verdict must be reduced by amounts "paid *or payable*" and amounts that "*may be reimbursed*," unlike the Florida statute that was interpreted by the three cases cited by Stevens in her cross-appeal. *Compare* MCA § 27-1-308 *with* Fla. Stat. Ann. § 768.76 (Reply App'x 5). Montana's rule expressly includes social security payments. MCA § 27-1-307. The district court correctly applied "logical deduction" to determine the appropriate amount of setoffs, *see Cottrell v. Burlington N. R.R. Co.*, 261 Mont. 296, 308-09, 863 P.2d 381, 388-89 (1993). (1/20/10 Opinion & Order 2-3.)

Conclusion

NPC seeks reversal and entry of judgment in its favor or, in the alternative, a new trial.

DATED this 1st day of July, 2010.

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 11(4) of the Montana Rules of Appellate Procedure and this Court's Order dated May 25, 2010, I certify that Appellant's Reply Brief is printed in a proportionally spaced Times New Roman text typeface of 14 points; is double spaced; and word count calculated by Word 2007 is 7,477 words, excluding the Table of Contents, the Table of Authorities, the Certificate of Service, and this Certificate of Compliance.

DATED this 1st day of July, 2010.

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I certify that on July 1, 2010, I served a copy of the preceding document on the following:

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